Complete Summary

GUIDELINE TITLE

Management of initial abnormal Pap smear.

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Management of initial abnormal pap smear. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2004 Jul. 45 p. [70 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Abnormal Pap smear

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Nursing
Obstetrics and Gynecology
Oncology

Pathology
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To provide recommendations for appropriate clinical follow-up for women who undergo cervical cytologic analysis and receive an abnormal Pap result
- To provide recommendations regarding colposcopic directed biopsy for women who are diagnosed with a high grade abnormal Pap smear
- To reduce the psychological distress and increase the knowledge of women who are notified of an abnormality on their Pap smear

TARGET POPULATION

Any woman or adolescent who has undergone cervical cytologic analysis (Pap smear) and has received an abnormal result

INTERVENTIONS AND PRACTICES CONSIDERED

1. Patient education regarding Pap smears and abnormal results
2. Routine Pap smear screening
3. Management based on classification of abnormal Pap smears. Options include repeat Pap smear, treatment of infections, intravaginal estrogen creams, colposcopy, endocervical curettage (ECC), endometrial biopsy; loop electrocautery excision procedure (LEEP); dilation and curettage (D & C); and cone biopsy
4. Consultation with gynecology or gynecologic oncology, when necessary

Note: Human papillomavirus (HPV) DNA testing is considered but not recommended as "standard of care" at this time.

MAJOR OUTCOMES CONSIDERED

- Incidence of abnormal Pap smear findings
- Risk of cervical and endometrial cancer in women with abnormal Pap smears

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

No additional description of literature search strategies is available.

NUMBER OF SOURCE DOCUMENTS

Not stated.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Clinical Validation-Pilot Testing
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Institute Partners: System-Wide Review

The guideline draft, discussion, and measurement specification documents undergo thorough review. Written comments are solicited from clinical, measurement, and management experts from within the member medical groups during an eight-week period of "Critical Review."

Each of the Institute's participating medical groups determines its own process for distributing the guideline and obtaining feedback. Clinicians are asked to suggest modifications based on their understanding of the clinical literature coupled with their clinical expertise. Representatives from all departments involved in implementation and measurement review the guideline to determine its operational impact. Measurement specifications for selected measures are developed by Institute for Clinical Systems Improvement (ICSI) in collaboration with participating medical groups following general implementation of the guideline. The specifications suggest approaches to operationalizing the measure.

Guideline Work Group: Second Draft

Following the completion of the "Critical Review" period, the guideline work group meets 1 to 2 times to review the input received. The original guideline is revised as necessary and a written response is prepared to address each of the suggestions received from medical groups. Two members of the Ob/Gyn Steering Committee carefully review the Critical Review input, the work group responses, and the revised draft of the guideline. They report to the entire committee their assessment of two questions: (1) Have the concerns of the medical groups been adequately addressed? (2) Are the medical groups willing and able to implement the guideline? The committee then either approves the guideline for pilot testing as submitted or negotiates changes with the work group representative present at the meeting.

Pilot Test

Medical groups introduce the guideline at pilot sites, providing training to the clinical staff and incorporating it into the organization's scheduling, computer, and other practice systems. Evaluation and assessment occur throughout the pilot test phase, which usually lasts for three months. Comments and suggestions are solicited in the same manner as used during the "Critical Review" phase.

The guideline work group meets to review the pilot sites' experiences and makes the necessary revisions to the guideline, and the Ob/Gyn Steering Committee reviews the revised guideline and approves it for implementation.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The recommendations for the management of abnormal Pap smear are presented in the form of nine algorithms, accompanied by detailed annotations. Algorithms are provided for: Test Result; Atypical Squamous Cells of Undetermined Significance (ASC-US); Atypical Squamous Cells of Undetermined Significance (ASC-US) with Special Circumstances; Atypical Squamous Cells - Cannot Exclude High-Grade Squamous Intraepithelial Lesion (HSIL) (ASC-H); Atypical Glandular

Cells of Uncertain Significance/Atypical Glandular Cells (AGUS/AGC); Low-Grade Squamous Intraepithelial Lesion (LSIL); Low-Grade Squamous Intraepithelial Lesion (LSIL) Adolescents; Low-Grade Squamous Intraepithelial Lesion (LSIL) Postmenopausal; and High-Grade Squamous Intraepithelial Lesion (HSIL). Clinical highlights and selected annotations (numbered to correspond with the appropriate algorithm) follow.

Class of evidence (A-D, M, R, X) ratings are defined at the end of the "Major Recommendations" field.

Clinical Highlights

1. Atypical squamous cells of undetermined significance (ASC-US) as an initial Pap result necessitates, at bare minimum, a repeat Pap smear within 6 months (though the provider may opt for a colposcopy). Other options include human papilloma virus (HPV) testing or immediate colposcopy. ASC-US on the repeat Pap smear would require colposcopic evaluation. (ASC-US Algorithm; Annotations #4, 5, 6)
2. Atypical glandular cells of uncertain significance/atypical glandular cells (AGUS/AGC) as an initial Pap result requires a colposcopy and endocervical curettage (ECC). Endometrial biopsy should be considered for women ≥35 years of age or if abnormal bleeding is present. If the results of the colposcopy, ECC, or endometrial biopsy are normal, follow-up evaluation should occur within 6 months. AGUS/AGC Pap results can, in some cases, be indicative of extracervical malignancy; therefore, aggressive follow-up is highly recommended. (AGUS/AGC Algorithm; Annotations #1, 2, 9)
3. Low-grade squamous intraepithelial lesion (LSIL) as an initial Pap result generally warrants a colposcopy. Special considerations may be made for adolescent and postmenopausal women. (LSIL Algorithm Annotations #1, 3; LSIL Adolescent Algorithm; LSIL Postmenopausal Algorithm)
4. High-grade squamous intraepithelial lesion (HSIL) as an initial Pap result requires colposcopy with biopsy and/or loop electrocautery excision procedure (LEEP). (HSIL Algorithm; Annotations #1, 2)

Test Result Algorithm Annotations

1. Abnormal Pap

   The guideline group recognized the difficulties faced by clinicians who must respond to abnormal Pap smears as reported by the Bethesda system. The group also recognized that there is a significant degree of variability in the approach to various diagnoses within the Bethesda system. Finally, the group realized that many patients are confused and perhaps unnecessarily alarmed when they receive a report of an abnormal Pap smear. It was the intention of the work group to provide a framework, based on objective evidence, that would provide guidance to the clinician and/or the patient facing an abnormal Pap smear result. Group efforts were hindered by the paucity of controlled randomized trials investigating various approaches to the follow-up of various cytologic diagnoses. The guidelines presented herein are recognized to be an interim effort based on critical review of existing data and on work group review consensus. Firm recommendations are anticipated to be available in the not-too-distant future as clinical studies currently underway provide more

accurate objective evidence. (See the original guideline document for the 2001 Bethesda System [Abridged] classification.)

Evidence supporting this recommendation is of class: R

2. Health Education

Patients should be informed of an abnormal result by physicians or by other health care personnel who answer basic questions and have sufficient training to allay undue anxiety.

Following verbal notification of an abnormal result, patients should be mailed written material specific to the diagnosis and recommended procedures/follow-up.

Evidence supporting this recommendation is of classes: A, C

3. Presence of Benign Endometrial Cells

The finding of benign endometrial cells (BEC) occurs in 12% of Pap smears from premenopausal women and 0.6 to 0.01% of postmenopausal women. The incidence varies with the phases of the menstrual cycle and the type of contraception used, as well as with the use or non-use of hormone replacement therapy. Bethesda 2001 guidelines recommend that pathologists report the presence of BEC in smears from women over the age of 40. This new reporting recommendation does not imply that it is abnormal to see endometrial cells in all women over 40, but, rather, reflects the fact that cytology laboratories do not reliably have access to accurate information about menopausal status. The clinician is therefore given the information so that he or she can determine the significance of the finding for the patient. No specific guidelines are offered for the management of BEC in postmenopausal women. The reported risk of endometrial cancer in postmenopausal women who underwent histologic evaluation within 24 months of such a Pap smear ranges from 0.8 to 21%. These figures are probably biased because the group of women undergoing endometrial biopsy or dilation and curettage (D&C) have a higher probability of cancer than women who did not have further evaluation. On this basis, the guideline group recommends that clinicians should review the menopausal status of women with a report of "benign endometrial cells in a woman over 40." If the woman is menopausal the guideline group recommends that she be specifically questioned about the presence of endometrial cancer symptoms, especially unexpected bleeding or spotting. If symptoms are present, endometrial tissue should be evaluated using endometrial biopsy or D&C. In the absence of symptoms a clinician might reasonably elect to continue with routine gynecologic care.

Evidence supporting this recommendation is of classes: B, C, D

Atypical Squamous Cells of Undetermined Significance (ASC-US) Algorithm Annotations

1. Atypical Squamous Cells of Undetermined Significance (ASC-US) Present

   The new Bethesda System has identified criteria for ASC-US on Pap screening. Atypical Squamous Cells of Undetermined Significance (ASC-US) is used by pathologists to denote cellular changes that are more marked than those attributable to reactive changes, but that are quantitatively or qualitatively short of a definitive diagnosis of Squamous Intraepithelial Lesion (SIL).

   Evidence supporting this recommendation is of classes: B, C, D, M, R, X

4. Repeat Pap Smear in 4-6 Months

   One option for the low-risk reliable patient with an ASC-US result would be to have a follow-up Pap test every 4 to 6 months until there have been two consecutive normal results, per the 2001 consensus guidelines. Then, routine testing can be resumed. Patients with abnormal Pap tests in the follow-up period should have colposcopy.

5. Colposcopy

   Controversy does exist in the area of management of ASC-US Pap smears. Some favor colposcopy for all ASC-US smears (after infection and atrophy have been treated appropriately; see the "Special Circumstances" Algorithm). Some practitioners have in the past favored colposcopy only for women with high-risk factors: teenage sexual activity, multiple sexual partners, intercourse with a male who has HPV, history of sexually transmitted disease or genital warts, tobacco use or history of tobacco use, intrauterine exposure to diethylstilbestrol (DES), poor compliance for follow-up, lack of normal immune response, no history of regular Pap smears, and age less than 30.

6. HPV Testing

   At this point, testing for HPV is not yet considered "standard of care," but some are advocating its use to help triage patients with ASC-US. It can be cost-effective when done in a setting that includes liquid-based Pap smear collection methods, since the residual fluid can be saved for HPV analysis rather than calling the patient back for sampling. Since HPV testing is another viable option for evaluation of the ASC-US Pap smear, colposcopy could be deferred and performed only for those women who have tested positive for intermediate or high-risk HPV types. Women with evidence of oncogenic HPV DNA should have whatever follow-up they would normally have depending upon their colposcopic diagnosis. Please see the "ASC-US Algorithm" Discussion and References, #6 in the original guideline document for more information.

8. Colposcopy

Colposcopy is recommended for any woman who has had an initial ASC-US Pap result followed by an abnormal Pap result of ASC-US or higher on follow-up.

11. Resume Routine Screening

    Mild or moderate inflammation and atrophic changes rarely progress to more abnormal pathology. Therefore, if the Pap smear is normal, resume routine screening. Severe inflammation has been associated with progression to more abnormal pathology.

12. High Risk HPV Type Isolated?

    Clinicians ordering HPV tests should be aware of the strengths and limitations of the assay. The report that clinicians will receive from the high risk assay will say that the patient tested positive or negative for "one or more of the following high-risk types" followed by a list of the HPV types. The careful wording is intended to convey to clinicians that the assay does not test for all HPV types known to associate with cervical cancer. A positive test for high-risk HPV types should indicate a need to educate the patient about HPV infection. A colposcopic examination should be scheduled. A negative HPV test result tells the clinician that the patient does not have a detectable burden of the high-risk virus types included in the test. The patient may, however, have a high-risk type at a lower titer than that which is reliably tested for or the patient may have an infection with a high-risk HPV type that is not part of the HPV assay. Clinical judgment and knowledge of the patient's health history and lifestyle should determine which women can return to routine screening on the basis of a negative HPV assay and which women might be considered for enhanced surveillance on the basis of the test result.

13. Colposcopy

    Refer to ASC-US Algorithm Annotation #8, "Colposcopy."

Atypical Squamous Cells of Undetermined Significance (ASC-US) with Special Circumstances Algorithm Annotations

2. Infection Present
3. Treat Infection and Repeat Pap in 4-6 Months

Per the 2001 Bethesda guidelines, pathologists will report infection as follows:

- Chlamydia
- Gonorrhea
- Trichomonas vaginalis
- Fungal organisms morphologically consistent with Candida species
- Shift in flora suggestive of bacterial vaginosis
- Bacteria morphologically consistent with Actinomyces species
- Cellular changes consistent with herpes simplex virus.

It is recommended to treat the infection present and repeat the Pap smear in 4 to 6 months.

4. Atrophy Present Postmenopausal
5. Treat Atrophy and Repeat Pap in 6 Months

Atrophic vaginitis can be a cause of atypical or low-grade Pap smears. Vaginal estrogen creams, applied 1 to 2 times per week for a minimum of six months, can effectively reverse atrophic changes. There is no need for concomitant progesterone therapy when using low-dose vaginal estrogen therapy. It is recommended to repeat the Pap smear within one week of completing vaginal estrogen therapy.

8. Repeat Pap in 12 Months

If the follow-up Pap smear at six months is normal, resume routine screening (no later than one year) for next Pap smear.

Atypical Squamous Cells - Cannot Exclude High-Grade Squamous Intraepithelial Lesion (HSIL) (ASC-H) Algorithm Annotations

1. Atypical Squamous Cells - Cannot Exclude HSIL

The 2001 Bethesda reporting system recognizes a new category of atypical squamous cells - cannot rule out high grade dysplasia (ASC-H). In the 1988 system, emphasis was placed on identifying all SIL Paps, including LSIL and HSIL. Currently, the emphasis of the 2001 Bethesda system is to identify HSIL and cytology associated with histologically proven high-grade disease.

ASC-H is thought to include 5 to 10% of all atypical squamous cells cases and includes mixtures of true HSIL and mimics. The positive predictive value of ASC-H in detecting cervical intraepithelial neoplasia (CIN) 2 and CIN 3 lies somewhere between 48 to 56%.

2. Colposcopy

Colposcopic examination is the established appropriate evaluation of women with ASC-H Pap smear reports. ECC should be performed if no lesion can be visualized. Initial evaluation of the ASC-H Pap smear should not routinely include the use of LEEP.

Atypical Glandular Cells of Uncertain Significance/Atypical Glandular Cells (AGUS/AGC) Algorithm Annotations

1. Atypical Glandular Cells of Uncertain Significance (AGUS/AGC)

Atypical glandular cells (which can be either uterine or cervical in origin) have enlarged nuclei, decreased cytoplasmic volume, and a variety of other unusual characteristics. In the new Bethesda system, "favor reactive change" has been dropped. AGUS/AGC becomes AGC (atypical glandular cells) with

one of the following subheadings: NOS (not otherwise specified), FN (favor neoplasia) and favor either endocervical or endometrial origin.

Evidence supporting this recommendation is of classes: C, D

2. Perform Colposcopy and Endocervical Curettage; Perform Endometrial Biopsy if ≥35 Years of Age or if Abnormal Bleeding

An AGUS/AGC Pap smear may be indicative of a precancerous change or a frank malignancy. Approximately one half of the patients will have a normal exam including colposcopy and ECC; however, 21 to 57% will have a clinically significant lesion. Results of two recent studies showed that 57% of patients had histological diagnoses, 37% had a significant lesion, and that the closer a practitioner looked for an abnormality, the more likely one would be found. Further, those patients having a previous diagnosis of CIN had an almost three-fold increase in findings of significant lesions in the current study. These numbers warrant a vigorous approach to evaluating these Pap smears. Some laboratories qualify AGUS/AGC abnormalities as favor reactive or favor neoplasm. Perform an endometrial biopsy to rule out endometrial cancer or hyperplasia in patients with abnormal bleeding or if 35 years of age and older. (A recent study showed correlation with significant lesions [60%] in postmenopausal women with only a 6% chance of significant lesions in premenopausal women.) Referral is appropriate for the portions of the evaluation the primary practitioner cannot complete.

Evidence supporting this recommendation is of classes: C, D

4. Treat Findings Appropriately

An abnormal Pap smear is not the only concern with an AGUS/AGC result. The same considerations for underlying abnormalities noted in the AGUS/AGC Algorithm Annotation #9 "Repeat Evaluation Within 6 Months" in the original guideline document also pertain here.

7. Cone Biopsy, Favor Cold Knife

Because of the increased chance of HSIL or endocervical lesion, the practitioner should perform a cone biopsy if the initial Pap smear result is reported as AGC-favor neoplasia. Additionally, the patient will need follow-up Pap smears 6 months apart until four consecutive normal results are recorded before the patient resumes routine screening protocols.

9. Repeat Evaluation Within 6 Months

Because there are no data to suggest appropriate follow-up when the evaluation is normal, except the suggestion that some portion of these patients will eventually develop clinically significant disease, the minimum follow-up for "normal" evaluations should be a Pap smear every 6 months until four consecutive normal results are recorded. When unable to demonstrate a colposcopic/biopsy abnormality after ACG Pap result, it may be helpful to consult with the pathologist to better define the nature of the

lesion. Repeat Paps are designed to pick up any undetected disease process before two years lapse. It is clear from continuing studies that these patients are at significant risk, especially when they have other predisposing findings such as a history of CIN, for having abnormality ranging from CIN to adenosquamous carcinoma to extracervical adenocarcinoma (including uterine, cervical, fallopian, ovarian, and even nongynecologic malignancies). AGUS/AGC or AGC findings in premenopausal women are ultimately much more likely to result in the diagnosis of SIL or adenocarcinoma than the same Pap smear result in a postmenopausal patient. If the Pap smear does not revert to normal on the follow-up Paps, further aggressive evaluation is indicated. The extensiveness of this evaluation is the subject of debate, and is left to the discretion of the provider. In fact, some practitioners feel that an AGUS/AGC result indicates some underlying disease process and that perhaps follow-up in the form of repeat Pap smears is less than adequate. Therefore, it is the recommendation of the work group that the minimum follow-up should consist of repeat Pap smears to occur 6 months apart until four consecutive normal results are recorded before the patient resumes routine screening protocols. If the subsequent Pap results are not normal, consultation with gynecology or gynecologic oncology is indicated.

11. Dilation and curettage (D & C)

    If the initial Pap smear result is reported as AGC-atypical endometrial cells, a fractional D & C is indicated, and referral to gynecology or gynecologic oncology should be initiated. Additionally, the patient will need follow-up Pap smears to occur 6 months apart until four consecutive normal results are recorded before the patient resumes routine screening protocols.

Low-Grade Squamous Intraepithelial Lesion (LSIL) Algorithm Annotations

1. Low-Grade Squamous Intraepithelial Lesion (LSIL)

   The Bethesda system combines mild dysplasia/CIN I with HPV into a single category of LSIL. Previously, it had been noted that approximately 60% of specimens with a diagnosis of LSIL represent processes that will regress spontaneously without treatment. However, more recent follow-up cytology studies have demonstrated both a high rate of loss to follow-up and a 53 to 76% likelihood of abnormal cytology and a small risk of delaying diagnosis of invasive cancer. Current recommended clinical practice is to perform a colposcopy unless special circumstances exist. An alternative is to repeat the Pap smear.

   Evidence supporting this recommendation is of class: R

3. Perform Colposcopy and Treat Appropriately

   The most common management option is to perform a colposcopy. One must be cautious about over-aggressive biopsy and treatment. Specifically, routine LEEP of the transformation zone as a method for evaluating a LSIL Pap smear is not recommended.

Evidence supporting this recommendation is of classes: C, R

Low-Grade Squamous Intraepithelial Lesion (LSIL) Adolescents Algorithm Annotations

1. LSIL Adolescents

   Most LSIL in adolescents is felt to be secondary to self-limited HPV infection.

   One research study suggests that HPV infection and subsequently mild cervical dysplasia will often resolve spontaneously. Persistence of abnormality on Pap warrants further colposcopic evaluation.

3. Repeat Pap Smear and HPV in 12 Months

   The ASCU/LSIL Triage Study for Cervical Cancer (ALTS) suggests that 83% of LSIL Paps are associated with high-risk HPV; therefore, initial HPV screening would not be useful. However, persistence of HPV at 12 months would indicate increased risk for CIN 2 and CIN 3 while resolution would indicate decreased risk.

Low-Grade Squamous Intraepithelial Lesion (LSIL) Postmenopausal - Algorithm Annotations

1. LSIL Postmenopausal
2. Evidence of Atrophy?

   Atrophy is a clinical diagnosis and can be caused by low-estrogen states including menopause, perimenopause, and long-term progesterone therapy.

3. Contraindication to Intravaginal Estrogen?

   Some women, such as those with estrogen receptor + breast cancer, may not be able to safely use intravaginal estrogen. The clinician and patient must review the risks and benefits of intravaginal estrogen use.

4. Prescribe Intravaginal Estrogen

   Effective vaginal estrogen therapy should include a six-month treatment period, and repeat Pap smear should be done within one week of cessation of therapy.

5. Repeat Pap Smear in 6 Months

   Postmenopausal women or women with cervical atrophy who have had previous regular and normal cytology have a higher likelihood of spontaneous regression than the general population.

9. Colposcopy

The most common management option is colposcopy. One must be cautious about over-aggressive biopsy and treatment.

High-Grade Squamous Intraepithelial Lesion (HSIL) Algorithm Annotations

1. High-Grade Squamous Intraepithelial Lesion (HSIL)

   The Bethesda system combines moderate dysplasia with severe dysplasia and carcinoma-in-situ (CIS) into a single category of high-grade intraepithelial lesion (HSIL). Up to 95% of patients with high-grade Pap smears have been found to have high-grade lesions.

   Evidence supporting this recommendation is of classes: C, M, R

2. Colposcopy with Biopsy and/or LEEP

   Colposcopic examination with directed biopsies or LEEP is the appropriate management for women with HSIL Pap smears. When a LEEP is performed immediately it is not necessary to automatically do an ECC. But if endocervical disease is suspected as a result of the colposcopy and LEEP is not done, an ECC should still be performed.

Definitions:

Classes of Research Reports:

A. Primary Reports of New Data Collection:

   Class A:

   - Randomized, controlled trial

   Class B:

   - Cohort study

   Class C:

   - Nonrandomized trial with concurrent or historical controls
   - Case-control study
   - Study of sensitivity and specificity of a diagnostic test
   - Population-based descriptive study

   Class D:

   - Cross-sectional study
   - Case series
   - Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

CLINICAL ALGORITHM(S)

Detailed and annotated clinical algorithms are provided for:

- Test Result
- Atypical Squamous Cells of Undetermined Significance (ASC-US)
- Atypical Squamous Cells of Undetermined Significance (ASC-US) with Special Circumstances
- Atypical Squamous Cells - Cannot Exclude High-Grade Squamous Intraepithelial Lesion (HSIL) (ASC-H)
- Atypical Glandular Cells of Uncertain Significance/Atypical Glandular Cells (AGUS/AGC)
- Low-Grade Squamous Intraepithelial Lesion (LSIL)
- Low-Grade Squamous Intraepithelial Lesion (LSIL) Adolescents
- Low-Grade Squamous Intraepithelial Lesion (LSIL) Postmenopausal
- High-Grade Squamous Intraepithelial Lesion (HSIL)

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The guideline contains an annotated bibliography and discussion of the evidence supporting each recommendation. The type of supporting evidence is classified for selected recommendations (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Improved clinical follow-up of women who receive an abnormal Pap smear

POTENTIAL HARMS

Not stated

CONTRAINDICATIONS

CONTRAINDICATIONS

Contraindication to Intravaginal Estrogen

Some women, such as those with estrogen receptor + breast cancer, may not be able to safely use intravaginal estrogen. The clinician and patient must review the risks and benefits of intravaginal estrogen use.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.
- This medical guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

IMPLEMENTATION TOOLS

Quality Measures

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

RELATED NQMC MEASURES

- Management of initial abnormal Pap smear: percentage of women diagnosed with an initial abnormal Pap smear who receive at least one clinical follow-up within six months of abnormality identified.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Management of initial abnormal pap smear. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2004 Jul. 45 p. [70 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 May (revised 2004 Jul)

GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

GUIDELINE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health System, Aspen Medical Group, Avera Health, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT Specialty Care, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty Healthcare, Grand Itasca Clinic and Hospital, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hutchinson Area Health Care, Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Mille Lacs Health System, Minnesota Gastroenterology, Montevideo Clinic, North Clinic, North Memorial Care System, North Suburban Family Physicians, Northwest Family Physicians, Olmsted Medical Center, Park Nicollet Health Services, Pilot City Health Center, Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, Saint Mary's/Duluth Clinic Health System, St. Paul Heart Clinic, Sioux Valley Hospitals and Health System, Southside Community Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians, Winona Clinic, Ltd., Winona Health

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GUIDELINE COMMITTEE

Ob/Gyn Steering Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Work Group Members: Lynne Lillie, MD (HealthEast Clinics) (Work Group Leader) (Family Practice); Steven Kind, MD (Park Nicollet Health Services) (Family Practice); Jo Reddy, MD (Northwest Family Physicians) (Family Practice); Lynn Stottler, MD (Gateway Family Health Clinic) (Family Practice); Lachlan Smith, MD, (Affiliated Community Medical Center) (Ob/Gyn); R. Paul Weatherby, MD (Park Nicollet Health Services) (Pathology); Corrine Esch, RN (HealthPartners Medical Group) (Nursing); Sylvia Robinson, BSN, MBA (Institute for Clinical Systems Improvement) (Measurement and Implementation Advisor); Nancy Greer, PhD (Institute for Clinical Systems Improvement) (Evidence Analyst); Jenelle Meyer, RN (Institute for Clinical Systems Improvement) (Facilitator)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

In the interest of full disclosure, Institute for Clinical Systems Improvement (ICSI) has adopted the policy of revealing relationships work group members have with

companies that sell products or services that are relevant to this guideline topic. The reader should not assume that these financial interests will have an adverse impact on the content of the guideline, but they are noted here to fully inform readers. Readers of the guideline may assume that only work group members listed below have potential conflicts of interest to disclose.

No work group members have potential conflicts of interest to disclose.

ICSI's conflict of interest policy and procedures are available for review on ICSI's website at www.icsi.org.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Institute for Clinical Systems Improvement (ICSI). Management of initial abnormal Pap smear. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2003 Apr. 47 p.

GUIDELINE AVAILABILITY

Electronic copies of the revised guideline: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

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